one immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, [BCG,] hemophilus influenza and smallpox.

73 (twice amended). The kit of claim 72 where said pediatric immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, a hepatitis B immunogen, and an immunogen which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, and polio.

144 (amended). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein at least one immunogen is provided which is not any of the following immunogens: a BCG, a hepatitis A, a hepatitis B, a *Hemophilus influenzae, Streptococcus pneumoniae* or *Neisseria* immunogen, or an immunogen of an organism which causes diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, influenza, cholera, plague, varicella, rabies, typhoid or yellow fever.

REMARKS

We previously filed an amendment after final rejection on

February 21, 2002, which was denied entry on June 4, 2002.

In response to the advisory action, we are filing three substitute amendments, of which this is one.

In the advisory action, the Examiner said that "amendments of the claims to add a hepatitis B immunogen and a herpes virus immunogen would raise new issues under 35 USC 112, second paragraph, as the metes and bounds of such immunogens are unclear".

Reviewing the claims, "hepatitis B" was added only by the amendment to claim 71. In the case of claims 5, 30, 56, 67, 73, 144, we merely shifted it from one Markush group to another in since the Examiner said that "the terms 'hepatitis A' and hepatitis B' are used in [typo in 67 "BCG, immunogen".] the art to designate etiologic agents which cause the disease hepatitis, rather than the disease itself.

With regard to herpes virus, claims 149-150 were amended to delete "herpes" from Markush group (a) and to insert "herpes virus" into Markus group (b). This was in response to the Examiner's comment that "the term 'herpes' is normally used to designate one of a specific group of viruses, rather than a disease per se". Note that claims 151-152 already recited "herpes virus" in their Markush group (b).

Here, we have omitted amending claim 71 to add reference to a "hepatitis B immunogen". Moreover, in view of the examiner's position on "herpesvirus", we have declined to amend claims 148 and 149. In our opinion, "herpes" is a name of a disease, and "herpes immunogen" connotes an immunogen native to an organism which causes herpes. We have no doubt that the causative organisms are herpesviruses, but "herpes" is still the disease.

We turn now to discussion of the underlying objection and indefiniteness rejection to which these amendments are directed.

2. Claims 5, 30, 56, 67, 71, 73 and 144 have been amended to resolve the "informalities in nomenclature".

3. The Examiner has not formally responded to our explanation that all members of the questioned markush groups (presumably, those of claims 5, 30, 37, 56, 67, 71 and 73) are immunogens, but that some are identified by their source organism directly, and others by the diseases with which they are associated (and hence may embrace immunogens from more than one organism). The wording of the objection suggests that this reasoning is accepted by the Examiner, so we do not understand why the rejection is maintained.

For further explanation, we direct the Examiner to pp. 12-16 of our August 17, 2001 amendment.

4. As a new ground of rejection (OA §6, p. 5) the Examiner asserts:

> Claims 5, 30, 32, 67, 71, 73, 77-85, 144, 149, 150, 151, and 152 recite "an immunogen of an organism" which causes one of a group of specifically recited diseases. The specification fails to teach what organisms are the etiologic agents of the recited diseases and fails to teach what is encompassed within an immunogen of the organism. Absent such disclosure, the metes and bounds of the claimed invention cannot be ascertained and the claims are indefinite.

We are not aware of any authority which requires that an immunogen be identified by source organism rather than by disease. For causative organisms, of various recited diseases, see pp. 13-15 of our August 17, 2001 amendment. This information is well known to those skilled in the art.

5. An errant comma in claim 67 has been deleted.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 5, 30, 56, 67, 71, 73 and 144 have been amended as follows:

5 (twice amended). The kit of claim 59 wherein one immunogen is provided which is not any of the following immunogens: a BCG, *Hemophilus influenzae, Streptococcus pneumoniae,* hepatitis A, hepatitis B, or *Neisseria* immunogen, or an immunogen of an organism which causes diphtheria, tetanus, pertussis, polio, [hepatitis A, hepatitis B,] measles, mumps , rubella, influenza, cholera, plague, varicella, rabies, typhoid or yellow fever.

30 (twice amended). The kit of claim 16 wherein said kit contains at least one immunogen selected from the group consisting of a *Hemophilus influenzae* immunogen, a BCG immunogen, a hepatitis B immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, polio, [Hepatitis B,] and pertussis.

56 (twice amended). A method of reducing the incidence or severity of an immune disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, where, when all of the immunogens administered are selected from

the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, a hepatitis B immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, pertussis, polio, [hepatitis B,] measles, mumps and rubella, at least one of the following conditions applies: (a) one or more immunogens are administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less, and
where one or more immunogens are administered on at least four different dates.

67 (twice amended). The kit of claim 66 where said pediatric immunogen is selected from the group consisting of a BCG[,] immunogen, a *Hemophilus influenzae* immunogen, a hepatitis B immunogen, and an immunogen which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, [hepatitis B,] and polio.

71 (twice amended). The kit of claim 43 in which at least one immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, [BCG,] hemophilus influenza and smallpox.

73 (twice amended). The kit of claim 72 where said pediatric immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, a hepatitis B immunogen, and an immunogen which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, [hepatitis B,] and polio.

144 (amended). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens,

according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein at least one immunogen is provided which is not any of the following immunogens: a BCG, a hepatitis A, a hepatitis B, a *Hemophilus influenzae, Streptococcus pneumoniae* or *Neisseria* immunogen, or an immunogen of an organism which causes diphtheria, tetanus, pertussis, polio, [hepatitis A, hepatitis B,] measles, mumps, rubella, influenza, cholera, plague, varicella, rabies, typhoid or yellow fever.